510(k) Summary

510(k) Number	K133680	
Submitter Name and Address		
Name	Siesta Medical, Inc.	
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Date Prepared	March 26, 2014	
General Device Information		
Product Name	ENCORE™ System	
Common Name	Bone Screw System	
Classification	21CFR872.5570 Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.	
Device Class	Class II	
Product Code	ORY	
Predicate Device		
Manufacturer	Device Name	510(k) Number
Siesta Medical, Inc.	ENCORE Tongue Suspension System	K121440
Medtronic, Inc.	AIRvance System	K122391
Device Description		
The ENCORE System is designed for anterior tongue base suspension by fixation of the soft tissue of the tongue base to the mandible bone and hyoid bone suspension to the mandible bone using a bone screw and suspension lines. The ENCORE System consists of 1) an integrated suture passer pre-loaded with size #2-0 braided polyester suture, 2) two (2) bone screws and bone screw inserters, 3) a suspension line lock tool, and 4) a threading tool. In addition, the following suspension lines are provided depending on the model number: 1) a #2 monofilament polypropylene suspension line with a radiopaque marker, 2) a size #2 braided polyester suspension line, and 3) a size #2 braided polyester suspension line with a radiopaque marker.		
Intended Use (Indications)		
The ENCORE System is intended to be used for anterior advancement of the tongue base. It is also suitable for performing hyoid suspension. It is indicated for the treatment of mild or moderate obstructive sleep apnea (OSA) and /or		

snoring.

Comparison to the Predicate Device

The ENCORE System has a modified intended use compared to the predicate devices. The intended use has been modified to include a statement that it is also suitable for the performance of a hyoid suspension procedure.

With regard to the modified intended use, similar to the predicate device, a needle is used to pass a suspension suture around the hyoid bone and a bone screw is used to anchor the suture with the desired amount of tension. The difference between the predicate device and the ENCORE System relates to how the suspension sutures are fixed once the desired level of advancement is achieved. In the predicate device, the suspension sutures are provided pre-attached to the bone anchors, which requires the tails of the suspension sutures to be joined or fixed at the midline of the hyoid bone with a knot once they are passed around the hyoid bone. With the ENCORE System the suspension sutures are passed around the hyoid bone and then attached to the bone anchors without the need to tie a knot.

The fundamental scientific technology and technological characteristics of the ENCORE System are the same as the predicate devices including mechanism of action, packaging, biocompatibility, sterilization, and labeling. The ENCORE System contains the same materials and components as the predicate ENCORE System. Through bench performance and clinical testing it was demonstrated that the modified intended use do not adversely affect safety and effectiveness.

Summary of Non-Clinical and Clinical Testing

The non-clinical test data provided in this submission demonstrated that the ENCORE System meets the performance specifications. The submission includes a Suspension Line Endurance Test and Bone Screw-to-Suspension Line Fixation Strength Test.

The non-clinical testing was performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices.

The clinical data provided in this submission includes a summary of eleven (11) clinical studies in 461 patients involving hyoid suspension published in the peer-review literature. There were few complications reports, with six studies reporting no significant intraoperative or post-operative complications.

This submission also includes an analysis of a series of patients treated for OSA

using hyoid suspension with the Encore System. This patient series included primarily males, with a mean age of 58.3 years, mean BMI of 27.9 kg/m^2, and a baseline AHI/RDI of 45.0. Hyoid suspension was successful in all patients. One patient had a post-operative wound seroma that resolved. Mean follow-up time was 75 days, with a reduction in AHI/RDI from 52.8 to 11.8 (78%, $p<0.01$).

The literature review and patient series shows that this treatment is often used successfully to reduce hypopharyngeal airway compromise, and may be used in combination with other surgical procedures (i.e., tongue suspension) that address additional sites of obstruction in the airway.

The use of hyoid suspension is an effective method to treat hypopharyngeal-based obstructions and can be used in combination with other procedures to effectively treat obstructive sleep apnea with or without tongue suspension.

Conclusion: The Encore System is physically identical to the predicate device, justifying no new nonclinical testing. Based on a review of the peer-review literature and a retrospective analysis of patients treated using hyoid suspension, we conclude that the Encore System is as safe and effective and performs as well or better than the predicate device.

Statement of Equivalence

The ENCORE System has similar indications for use and the same technological characteristics as the predicate devices. Based on this and the data provided in this pre-market notification, the subject device and the predicate device have been shown to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 26, 2014

Siesta Medical, Incorporated
Mr. Michael Kolber
Vice President, Regulatory Affairs
101 Church Street, Suite 3
Los Gatos, California 95030

Re: K133680
Trade/Device Name: ENCORE™ System
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: II
Product Code: ORY
Dated: December 31, 2013
Received: January 2, 2014

Dear Mr. Kolber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Siesta Medical, Inc. ENCORE™ System

The ENCORE System is intended to be used for anterior advancement of the tongue base. It is also suitable for performing hyoid suspension. It is indicated for the treatment of mild or moderate obstructive sleep apnea (OSA) and /or snoring.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
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